



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0120]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0599. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Cosmetic Labeling Regulations--21 CFR part 701 (OMB Control Number 0910-0599)--

Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products.

Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 331, 352, 361, 362, 363, 371, and 374, respectively) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

FDA's cosmetic labeling regulations are published in part 701 (21 CFR part 701). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

In the Federal Register of April 17, 2014 (79 FR 21766), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third Party Disclosure Burden¹

21 CFR Section/ Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
701.3/Ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11/Statement of identity	1,518	24	36,432	1	36,432
701.12/Name and place of business	1,518	24	36,432	1	36,432
701.13/Net quantity of contents	1,518	24	36,432	1	36,432
Total					141,174

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: A declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

The estimated annual third party disclosure is based on data available to the Agency, our knowledge of and experience with cosmetic labeling, and our communications with industry. We estimate there are 1,518 cosmetic product establishments in the United States. We calculate label design costs based on stock keeping units (SKUs) because each SKU has a unique product label. Based on data available to the Agency and on communications with industry, we estimate that cosmetic establishments will offer 94,800 SKUs for retail sale in 2014. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that we discuss in this information collection, §701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. We estimate that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the Agency's experience with other products, we estimate that cosmetic establishments may redesign up to one-third of SKUs per year. Therefore, we estimate that the number of disclosures per respondent will be 21 (31,878 SKUs) for §701.3 and 24 each (36,432 SKUs) for §§701.11, 701.12, and 701.13.

We estimate that each of the required label elements may add approximately 1 hour to the label design process. We base this estimate on the burden hours the Agency has previously estimated for food, drug, and medical device labeling and on the Agency's knowledge of cosmetic labeling. Therefore, we estimate that the total burden hours on members of the public for this information collection are 141,174 hours per year.

Dated: June 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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